Department of Health and Human Services Public Health Service

Food and Drug Administration
Rockville, MD 20857

MAY 25 1999

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Richard A. Shupack
Associate General Counsel
Elan Pharmaceuticals
800 Gateway Blvd.
South San Francisco, CA 94080

Re: Docket No. 98P-1191/CP1 & PSA1

Dear Mr. Shupack:

I am writing to inform you that the Food and Drug Administration has not yet resolved the issues raised in your citizen petition submitted on December 15, 1998 and amended January 15, 1999. Your petition as amended requests that the Agency require abbreviated applications for approval of controlled release naproxen sodium products referencing Naprelan to include specific information to demonstrate that the generic products include:

1. Data necessary to demonstrate equivalent early onset of analgesia, and,
2. Evidence consisting of the results of comparative scintigraphy or endoscopy studies to demonstrate equivalent absence of potential excessive GI toxicity, or other evidence that adequately addresses the GI toxicity issue.

In a separate petition for stay of action received December 15, 1998, Elan requested the FDA stay the approval of any ANDA referencing Naprelan unless and until it includes the information above.

FDA has been unable to reach a decision on your requests due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your requests as soon as possible given the numerous demands on the Agency's resources.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

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